PredicineBEACON™

CLIA Validated Tissue-Agnostic, Personalized, Actionable MRD Assay

Sensitive Minimal Residual Disease (MRD) detection not limited by baseline tissue sample availability

50

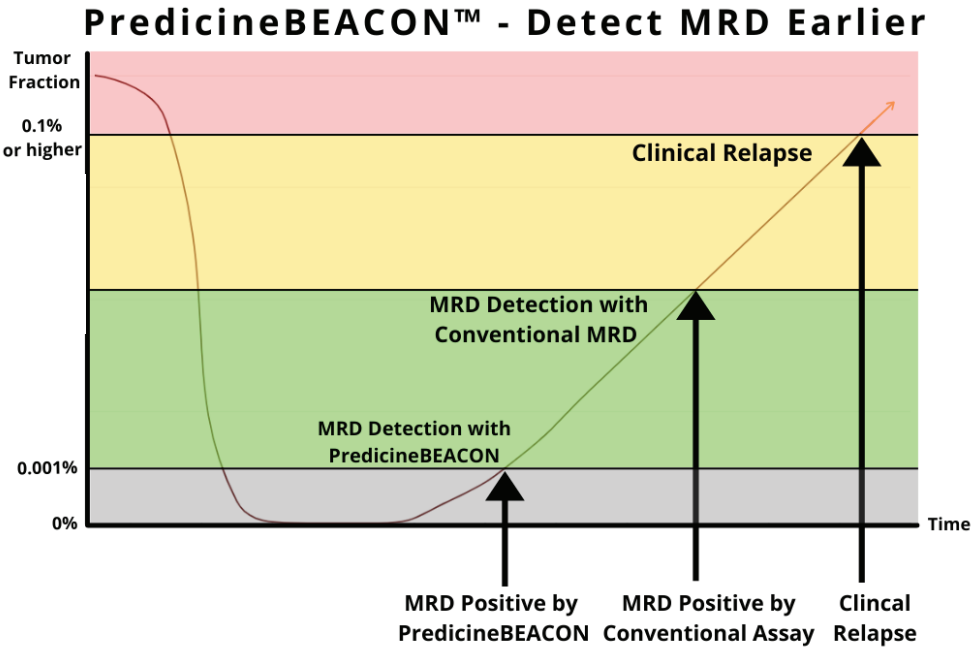
Up to 50 personalized mutations

500

Actionable and hotspot mutations tracked

≥0.001%

Tumor Fraction



Methods and Reporting

- Flexibility in baseline profiling: tissue or liquid biopsy (including blood, plasma, and urine)
- Sensitive MRD detection: limit of detection as low as 0.001% tumor fraction, when personalized panel contains 50 mutations
- Includes genome-wide copy number changes including copy number reductions
- Longitudinally tracks up to 50 personalized mutations
- Includes analysis of 500 actionable and hotspot mutations

Workflow

Baseline sample collection | Baseline variant profiling | Longitudinal MRD tracking | Sensitive MRD detection | Patient report: actionable MRD

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PredicineBEACON™ addresses the challenges faced by conventional MRD assays

- Tissue agnostic solution: Baseline analysis can be obtained via blood, urine, or tissue
- High sensitivity: Ability to identify alterations missed by less sensitive assays
- Multidimensional: Detects all types of DNA changes, including fusions and copy number changes
- Actionable MRD result: Upon recurrence, actionable and hotspot mutation analysis may provide clinically relevant information to guide treatment decisions

Product Details

Baseline Profiling
Blood, Urine, or Tissue

Multi-Dimensional MRD Detection
Mutations, Fusions, and Copy Number Changes

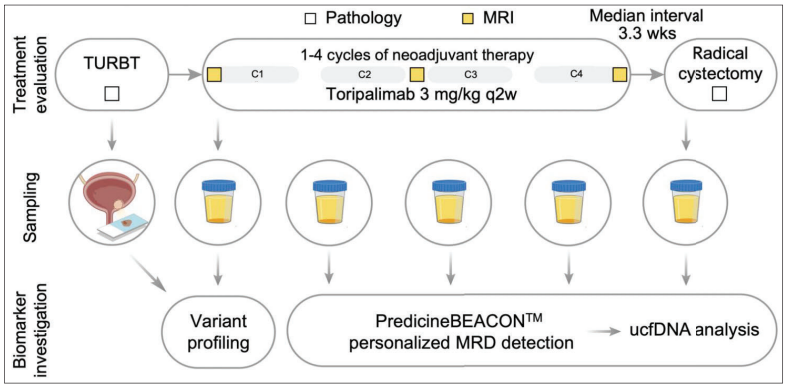
High Sensitivity
0.001% Tumor Fraction Limit of Detection

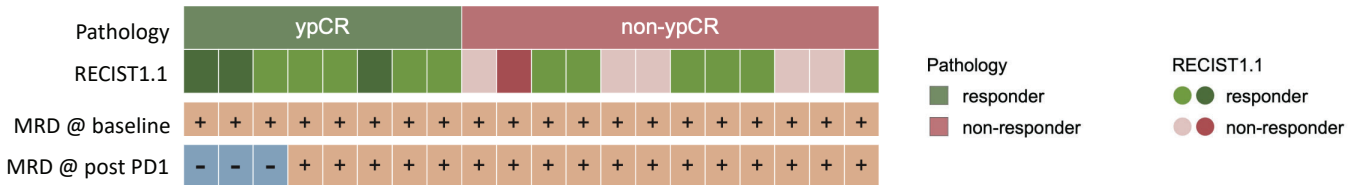
Actionable MRD
500 Actionable and Hotspot Mutations

Case Study: Tissue-free, urine-informed MRD in neoadjuvant MIBC

Longitudinal personalized urinary tumor DNA analysis in muscle invasive bladder cancer from neoadjuvant immunotherapy trial RJBLC-I2N003[1]

Study design





Conclusion:

PredicineBEACON™ urine-based MRD biomarker assessment identified MRD-positive patients that achieved pathological complete response (pCR), demonstrating the potential clinical utility of longitudinal personalized urinary tumor DNA (utDNA) analysis to complement existing trial endpoints. This study suggests that a urine-based MRD test could be used to identify MRD-negative MIBC patients after neoadjuvant therapy who could potentially avoid radical cystectomy.

[1]Zhang, et al. Longitudinal peronsalized urinary tumor DNA analysis in muscle-invasive bladder cancer from the neoadjuvant immunotherapy trial RJBLC-IN003. Journal of Clinical Oncology. Volume 40, Issue 6 supplemental. 2022.